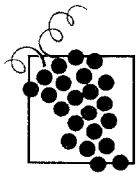

grapevine
TRADING COMPANY

'00 JUL 11 A10:15

June 20, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Nos.: 92N-0297 and 88N-0258
Rule on 21 CFR Parts 203 and 205

Dear Sir or Madam:

The FDA has asked for comments regarding the economic impact of the provisions of the proposed rule on smaller wholesale distributors that are not authorized distributors. Grapevine Trading Co. (Grapevine) is sure that the FDA will receive many comments on the costs to "unauthorized distributors" of complying with the proposed rule. Grapevine dittos these comments and, will, like the other 4000 small drug distributors, face the strong possibility of the loss of business and jobs if the rule remains unchanged. Grapevine would like to address another economic issue, the cost to the public, if the FDA rule goes into effect.

The many small distributors of drugs in the United States that would fall into the category of "unauthorized distributors" play an important function in the U.S. economy. They assure open, fair and aggressive price competition in the sale of drugs to pharmacies, hospitals, clinics, doctors and other retail drug purchasers. At a time when this country faces a severe crisis in the rising cost of prescription drugs[1], the elimination of these aggressive competitors could exacerbate the problem. Moreover, these small distributors provide service to their customers, including overnight delivery of the increasingly expensive infusion products and other drugs that sustain life. These drugs are too expensive to be inventoried by most health care providers. Small distributors deliver these drugs promptly so that they can be dispensed or given to the patient and reimbursed promptly.

[1] Consumers Union reported on November 3, 1999 that the prices of the 50 most prescribed drugs for older Americans increased four times the rate of inflation for the period from January 1998 to January 1999. President Clinton in his April 29, 2000 weekly radio address referring to these numbers said "Seniors and people with disabilities living on fixed incomes simply cannot continue to cope with these kinds of price increases."

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92N-0297 C119

It is no secret that prescription drug manufacturers and their hand-picked principal wholesale customers have been involved in a number of anticompetitive activities aimed at stifling competition. In March of this year, the Federal Trade Commission sued Hoechst Marion Roussel (now known as Aventis) alleging that Hoechst entered into an illegal agreement with Andrx to forestall Andrx's introduction of a generic competitor to Hoechst's Cardizem CD. At the same time, the FTC sued Abbott Laboratories alleging that Abbott had entered into a similar illegal arrangement with Geneva Pharmaceuticals to delay Geneva from bringing to the market a generic alternative to Hytrin. Last year, the Commission sued Mylan Laboratories alleging that Mylan had monopolized and attempted to monopolize the production of certain drugs by entering into illegal agreements to keep key drug ingredients out of the hands of Mylan's competitors. The Commission charged that this illegal conduct allowed Mylan to increase prices for clorazepate and lorazepam by 25 to 30 times the original wholesale prices.

Additionally the government is presently investigating drug industry pricing practices. It is common knowledge in the drug distribution marketplace (but apparently not to the United States government) that average wholesale prices or "AWP" are artificially high or inflated. AWPs are set so high so that the manufacturers may give deep discounts, rebates and incentives to certain preferred customers, such as doctors, managed care groups and large health plans. The federal government is contending that these same discounts are not provided to it, a violation of law. The Wall Street Journal reported on May 10, 2000, that Medicare and Medicaid may have over paid one manufacture alone, Bayer, $1 billion or more a year because of these deceptive pricing practices.

The government's concerns about anticompetitive activity are not limited to the drug manufacturers. In 1998, the FTC blocked mergers between Cardinal Health and Bergin Bruswig Corp., and between McKesson Corp. and Amerisource Health Corp., four of the nation's largest drug wholesalers, on the grounds that the transactions would adversely affect competition in the drug wholesale market.

Most amazing is that the U.S. Department of Health and Human Services (HHS) itself raised these same concerns in its opposition to the enactment of the Prescription Drug Marketing Act (PDMA). Otis R. Bowen, M.D., then Secretary of the Department of Health and Human Services in a letter dated April 11, 1988 addressed to James C. Miller, Director of the Office of Management and Budget indicated that HHS believed it "inappropriate to address an economic issue, in this case competition, through a public health statute" (Exhibit A). Secretary Bowen stated:

> **"Despite concerns expressed by the bill's sponsors, little actual risk to the public health has been shown to be linked with the business practices this legislation is designed to curb. To the extent that reimported or redistributed drugs might be subpotent, outdated,**

mislabeled, or counterfeit, the Department's Food and Drug Administration (FDA) has ample authority to deal with these problems under current law."

Twelve years later the FDA is revisiting the issue of whether its role is to address economic issues through a public health rule. We contend that the rules remain an inappropriate forum to address essentially economic issues.

The potential elimination of 4,000 independent drug wholesalers that is likely to occur if the FDA rule becomes effective can adversely affect competition in several ways. First, many of these small distributors provide meaningful price competition to the large wholesalers who would likely be the only remaining wholesalers if the FDA rule becomes effective. Less competition means higher prices. Second, fewer resellers would make it easier for drug manufacturers to maintain desired prices (and police any deviations from their oligopolisitic pricing policies) by controlling the prices at which the drug wholesalers resell their drugs. The control of resale prices can be very important to manufacturers trying to maintain coordinated pricing. This is why minimum resale price maintenance is *per se* illegal under the Sherman Act. It is much easier for the drug manufacturers to control resale prices if they only have to deal with a few, large wholesalers. Indeed the threat of withdrawing authorization would be a powerful tool to keep the large wholesalers in line.

One of the bedrock principles of the free market system is that competition flourishes when there are more competitors. Existing licensure requirements and laws establishing federal civil and criminal penalties for distribution of prescription drugs without licenses or distribution of adultered drugs are sufficient to prevent outdated, counterfeit or mislabeled drugs from entering into commerce. As Secretary Bowen stated in 1988, the "FDA has ample authority to deal with these problems under current law." This has not changed in the last 12 years. The FDA needs to think long and hard about a rule that could eliminate 4000 competitors in one fell swoop.

Very truly yours,

Grapevine Trading Co.

David A. Kantor
President

Enclosure

EXHIBIT A

HHS Bill Report; 1988; H.R.1207; **Prescription Drug Marketing Act**

APR 11 1988

The Honorable James C. Miller III
Director, Office of Management
and Budget
Washington, D.C. 20503

Dear Mr. Miller:

This is in response to your request for a report on H.R. 1207, an enrolled bill entitled the "**Prescription Drug Marketing Act** of 1987".

We recommend that the President approve the enrolled bill. Given the overwhelming congressional support for the bill, we believe it would be pointless for the President to disapprove it, although we believe the bill inappropriately addresses an economic issue through a public health statute, and would divert enforcement resources from the task of protecting the public health.

H.R. 1207 would amend the Federal Food, **Drug**, and Cosmetic **Act** (FFD&C **Act**) to prohibit the reimportation of American-made pharmaceuticals except by the manufacturer or in an emergency; prohibit the trading, selling or purchasing of **drug** samples and coupons and the counterfeiting of such coupons; prohibit the resale of pharmaceuticals by hospitals and charitable organizations except under certain conditions; restrict the distribution of **drug** samples by sales representatives and permit an alternative distribution system by mail or common carrier; require Federal standards for the licensure of **drug** wholesalers; and establish civil and criminal penalties for violations of these provisions.

The rationale given for H.R. 1207 is to reduce potential public health risks that may result from **drug** counterfeiting, the **marketing** of reimported drugs, and the redistribution of drugs intended to be used as samples as well as drugs being bought and sold by certain non-profit institutions. The bill's sponsors have stated the intent to reduce the risk, such as it may be, that drugs will become ineffective or otherwise adulterated as a result of "gray market" diversion. It is our understanding that this legislation is also intended, and in any case its effect will be, to eliminate a source of competition in the domestic **drug** market through the diversion into the domestic market of **prescription** drugs which have been sold at prices below the domestic wholesale price either for export, to non-profit health facilities, or for promotional purposes.

Despite concerns expressed by the bill's sponsors, little actual risk to the public health has been shown to be linked with the business practices this legislation is designed to curb. To the extent that reimported or redistributed drugs might be subpotent, outdated, mislabeled, or counterfeited, the Department's Food and **Drug** Administration (FDA) has ample authority to deal with these problems under current law.

In the absence of any significant public health issue, we believe it is inappropriate to address an economic issue, in this case competition, through a public health statute like the FFD&C **Act**. We are also concerned that H.R. 1207 may impose on FDA (and on its counterpart State and local agencies) substantial costs not justified by the largely speculative risks connected with **drug**

diversion, and the withdrawal of resources from tasks more critical to the agency's mission of ensuring a safe and effective **drug** supply.

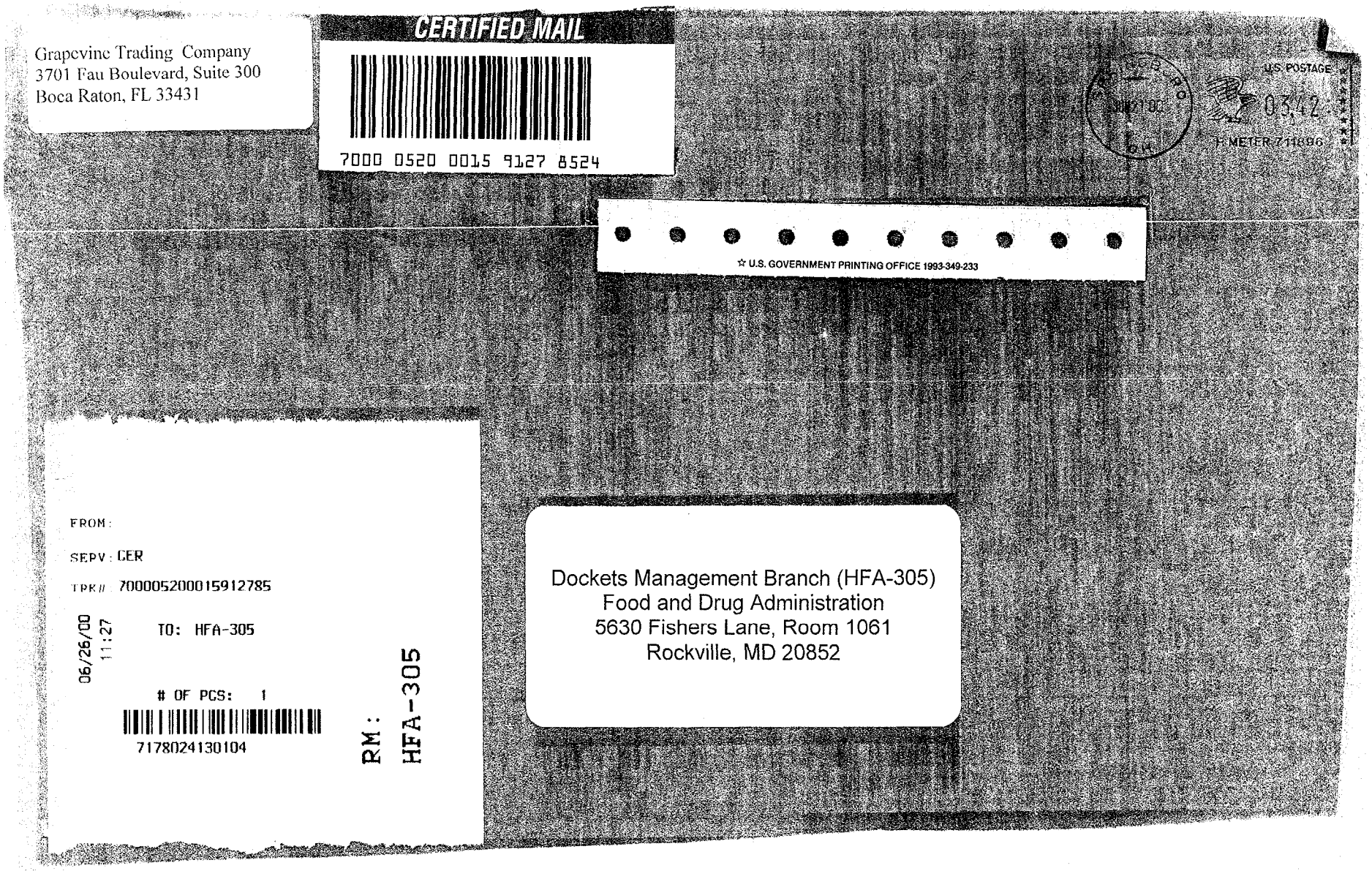
For the foregoing reasons the Department opposed enactment of the bill during its consideration by the Congress.

Nevertheless, we note that the bill has overwhelming bipartisan support in both House and Senate. The bill was introduced in the House by the Chairman of the Committee on Energy and Commerce, and had 40 additional cosponsors, including the chairman of the subcommittee within Energy and Commerce with legislative jurisdiction over the Department. The companion bill in the Senate had 27 cosponsors. The bill passed both Houses by voice votes, virtually without opposition. In these circumstances it is virtually certain that a veto of the bill would be overriden, and would only serve to strain our relations with the Congress and in particular with the House Committee.

We therefore recommend that the President approve the enrolled bill.

Sincerely,

/s/ Otis R. Bowen, M.D.
Secretary



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